

# STATE BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS PUBLIC BOARD MEETING DRAFT MINUTES

**DATE:** February 6-7, 2018

**LOCATION:** Department of Consumer Affairs

1<sup>st</sup> Floor Hearing Room 1625 North Market Blvd. Sacramento, Ca 95834

**BOARD MEMBERS** 

PRESENT: Victor Law, RPh, Vice President

Allen Schaad, RPh, Treasurer Greg Lippe, Public Member Valerie Muñoz, Public Member

Amy Gutierrez, PharmD, President

Deborah Veale, RPh

Ryan Brooks, Public Member

Albert Wong, RPh

Lavanza Butler, RPh (February 6 only)

Stanley Weisser, RPh

**BOARD MEMBERS** Amjad Khan, Public Member **NOT PRESENT:** Ricardo Sanchez, Public Member

**STAFF** Virginia Herold, Executive Officer

**PRESENT:** Anne Sodergren, Assistant Executive Officer

Laura Freedman, DCA Counsel Kelsey Pruden, DCA Counsel

Joshua Room, Supervising Deputy Attorney General

Laura Hendricks, Staff Analyst

# I. Call to Order, Establishment of Quorum and General Announcements

President Gutierrez called the meeting to order at 10:30 a.m. Board members present: Gregory Lippe, Albert Wong, Deborah Veale, Allen Schaad, Lavanza Butler, Victor Law, Amy Gutierrez, Valerie Munoz, Ryan Brooks and Stanly Weisser.

# II. Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings

There were no comments from the board or from the public.

### III. November 8-9, 2017 Board Meeting Minutes

Ms. Veale noted that her name is spelled incorrectly on page 6 of the minutes.

Mr. Lippe noted that on page 10, the following sentence needs to be corrected.

Ms. Herold explained that in recent weeks, there have been a number of announcements involving the regulation of controlled of controlled substances over the last years.

**Motion:** Approve the November 2017, board meeting minutes with the changes noted by the board.

M/S: Veale/Law

Support: 7 Oppose: 0 Abstain: 3

<b>Board Member</b>	Support	Oppose	Abstain	Not Present
Brooks			х	
Butler	х			
Gutierrez	х			
Khan				х
Law	х			
Lippe	х			
Munoz			х	
Sanchez				х
Schaad	х			
Veale	x			
Weisser			х	
Wong	х			

### IV. <u>December 12, 2017 Board Meeting Minutes</u>

**Motion:** Approve the December 12, 2017, board meeting minutes.

M/S: Law/Veale

Support: 6 Oppose: 0 Abstain: 4

<b>Board Member</b>	Support	Oppose	Abstain	Not Present
Brooks			х	
Butler	х			
Gutierrez			х	
Khan				х
Law	х			
Lippe	х			
Munoz			Х	

Sanchez			Х
Schaad	х		
Veale	х		
Weisser		х	
Wong	х		

# V. January 11, 2018 Board Meeting Minutes

President Gutierrez stated that the following sentence on page 11 of the minutes needs to be corrected.

"Ms. Veale noted that these machines would be very helpful in medically underservedissues areas."

**Motion:** Approve the January 11, 2018, board meeting minutes including the corrections noted by the board.

M/S: Weisser/Law

Support: 8 Oppose: 0 Abstain: 2

<b>Board Member</b>	Support	Oppose	Abstain	Not Present
Brooks			х	
Butler	х			
Gutierrez	х			
Khan				х
Law	х			
Lippe	х			
Munoz			х	
Sanchez				x
Schaad	х			
Veale	х			
Weisser	х	_		
Wong	х			

# VI. Recognition and Celebration of Pharmacists Licensed in California for 50 Years

There were no 50-year pharmacists in attendance.

### VII. Update from the Department of Consumer Affairs

# a. Explanation of the "Pre-Notice Review" Process Conducted on Regulations

Ryan Marcroft, Deputy Director of Legal Affairs, provided the board with an overview of the regulation process.

**Note:** a flow-chart of the regulation process provided to the board by Mr. Marcroft is provided immediately following these minutes.

Mr. Marcroft explained that DCA is focusing on reducing the number of regulations disapproved by OAL. He stated that the "pre-notice review" conducted by the DCA legal office is intended to help reduce the disapprovals.

The board stated that recently the regulations have been taking more time to be completed and asked if the pre-notice review was a new process implemented by DCA. Mr. Marcroft responded that it was not a new process. Ms. Sodergren noted that in her experience the board has not previously been required to have its regulations pre-reviewed by DCA legal before beginning the regulation process.

The board expressed their frustration with the length of time that it takes the department to review regulations. They specifically noted that the board's emergency compounding regulation as approved by the board in July of 2017 and it did not complete the prenotice review until the end of November 2017.

Daniel Martinez stated that CPhA sent a letter to the DCA executive office expressing their concern that the emergency regulation was taking so long to be reviewed by the department.

The board asked Mr. Marcroft if there is standard processing time that the DCA legal office uses for their pre-notice review. Mr. Marcroft stated that the review time is dependent on how complex the regulation is.

The board again stressed the importance of improving the processing time for review of regulations. The board asked that Ms. Sodergren work with the DCA legal office to develop a way to track the regulations as they move through the various levels of approval within the department and OAL.

#### b. Business Modernization Efforts

Mr. Piccione explained that business modernization is the initiative to address the potential gaps and deficiencies of modern business processes for the boards and bureaus that were not implemented on the Breeze platform.

Mr. Piccione provided a timeline of the BreEZe project as provided below.

- 2008 2011: Early Breeze Project Planning and Approvals
- 2012 Oct 2013: Development and Implementation of BreEZe release 1, including 10 boards and bureaus
- 2014 Jan 2016: An update of the plans and strategies for the initiative,
   Development, Training and Implementation of BreEZe release 2, including 8 boards and bureaus
- Late 2014, with an official date of January 2015, the 18 remaining boards and bureaus were de-scoped from the BreEZe project

Mr. Piccione stated that the board was removed from release 2 primarily based on functionality gaps that could not be overcome in a cost-effective manner.

Mr. Piccione reported that in 2017, the department began to consider how to address the boards and bureaus that were de-scoped from BreEZe. As a result, the department drafted the Business Modernization Plan and individual Business Modernization Reports.

Mr. Piccione explained that the Business Modernization Plan is a single document for the entire department that sets out lessons learned, guiding principles, and guardrails for each programs' initiative. The Business Modernization Reports are collaborative, fundamental documents that address each program *individually* and provide a living document to react, flex and reflect the program itself. He further explained that the effort is solely based on the needs of the Board of Pharmacy, not an aggregate or composite of perceived departmental needs.

Ms. Sodergren noted that board staff has already begun working with the department to identify the board's business modernization needs and will continue to provide updates to the board as the project moved forward.

Note: Ms. Veale left the room at 11:08 a.m.

#### c. Credit Card Payments for Boards Using the Legacy System

Mr. Piccione stated stakeholders have identified two clear objectives that can't wait for the conclusion of the Business Modernization effort: data analytics and credit card acceptance. He explained that the Department has already established a very successful data analytics platform for data housed within the BreEZE platform. He stated that the department is currently expanding that platform to also house the legacy mainframe data so boards not using BreEZe can utilize the valuable data assets at its disposal.

Mr. Piccione stated that the department recognizes that the lack of credit card acceptance is a significant problem for boards not using BreEZe. He explained that while credit card acceptance for all transactions is the ultimate goal, establishing credit card acceptance for renewals has been made a priority.

Mr. Piccione reported that due to contract problems the timeline for credit card acceptance was delayed; however, it is now back on track for a targeted release of late Fall/Early Winter 2018.

The board stated that credit card acceptance is a top priority for the board and thanked Mr. Piccione for working to implement the program.

# d. Update on the New Fi\$cal System

Taylor Schick, budget officer for DCA, explained that the entire state is converting to a new online accounting and budgeting system called Fi\$cal.

Mr. Schick explained that because of the conversion to the new Fi\$cal system that went live on July 1, 2018, there has been a significant delay in the reports the budget

office receives. He also explained that the budget office has had to complete extensive audits of the reports to validate the information.

Ms. Schick stated that so far, they have been able to validate the first two fiscal months for FY 17/18.

The board asked that Ms. Sodergren continue to work with the budget office to validate the information received from FiScal.

#### e. Update on the Board's Budget

Mark Ito, budget manager, provided the board with a fund condition. Note: a copy of the fund condition has been provided following these minutes.

The board expressed their concern that the fund condition showed that by FY 18/19 the board would only have 2.3 months in reserve. Ms. Sodergren noted that because of the Fi\$cal conversion board staff has not been provided any budget information for FY 17/18.

Mr. Ito stated that the new Fi\$cal system has made it difficult for the budget office to assist board's in keeping track of their fund conditions.

The board asked that Ms. Sodergren work closely with the budget office to verify the board's revenue and expenditures and to monitor the board's fund condition.

The board recessed for a break at 11:55 a.m. and resumed at 12:05 a.m.

#### VIII. Legislation and Regulation Committee

Chairperson Lippe provided a summary of the committee meeting that had occurred immediately prior to the board meeting.

Chairperson Lippe explained that the Legislature reconvened on January 3, 2018. February 16, 2018, is the last day for bills to be introduced. He added that because this is the second year of a two-year legislative cycle, legislative deadlines for proposals from last year vary from deadlines for newly introduced measures.

Note: A copy of the 2018 tentative legislative calendar was provided in the board meeting materials.

#### Part 1: Legislation for Discussion and Consideration Report

#### a. Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction

1. AB 1659 (Low) Healing Arts Boards, Inactive Licenses

Version: As amended January 3, 2018

Status: January 31, 2018 Referred to the Senate

**Summary**: This measure would prohibit a person with an inactive license from representing that he or she has an active license. This measure would also allow a

healing arts board to establish a lower inactive license renewal fee.

**Staff Comments**: This measure is being brought to the committee to seek input on the policy of the measure. Based on the policy discussion board staff will identify what, if any fiscal impact would occur.

Chairperson Lippe reported that the committee voted to support AB 1659; however, the motion did not pass.

Chairperson Lippe explained that some members felt that licensees that are inactive should not have to pay the same renewal fees. He added that other members expressed concern with how the board's budget may be negatively impacted if the fees are reduced.

Ms. Sodergren reported that approximately 5,000 pharmacists currently have an inactive license. Ms. Freedman added that a pharmacist can also choose to pay a one-time fee to retire their license.

Ms. Sodergren explained that an inactive pharmacist must complete 30 hours of CE before they can return their license to active status. Chairperson Lippe noted that the committee asked that the Licensing Committee review the requirements for pharmacists to return to active status to determine if they are appropriate.

Ms. Butler stated that pharmacists who choose to place their license on inactive status should not have to pay the same renewal fee as active pharmacists.

Ms. Butler made a motion to support AB 1659.

Mr. Weisser and Ms. Munoz expressed concern with supporting the bill without information on how the board's budget would be effected by reducing fees.

Based on comments made by the board Ms. Butler withdrew her motion and asked staff to provide information on how reducing fees for all individual licensees will impact the board's budget.

Ms. Veale asked if the board would have time to take a position on the bill before the legislative deadline. Ms. Sodergren stated that per the board's policy, the committee chair and board president could take a position on the bill based on the budget information provided by staff.

#### 2. AB 1751 (Low) Controlled Substances: CURES Database

Version: As introduced January 3, 2018

**Status**: Referred to Assembly Business and Professions Committee **Summary**: This measure will allow the Department of Justice to enter into an agreement with an entity operating an interstate data share hub for purposes of interstate sharing of controlled substances reporting information.

Chairperson Lippe reported that the committee took a support position on AB 1751.

The board also expressed support for AB 1751. There were no comments from the public.

# Committee Recommendation (Motion): Support AB 1751.

Support: 10 Oppose: 0 Abstain: 0

<b>Board Member</b>	Support	Oppose	Abstain	Not Present
Brooks	х			
Butler	х			
Gutierrez	х			
Khan				Х
Law	х			
Lippe	х			
Munoz	х			
Sanchez				х
Schaad	х			
Veale	х			
Weisser	х			
Wong	х			

### 3. AB 1752 (Low) Controlled Substances: CURES Database

Version: As introduced January 3, 2018

Status: Referred to Assembly Business and Professions Committee

**Summary**: This measure expands CURES reporting to also include Schedule V controlled substances as well as other medications of concern identified by the board in regulation. The measure also reduces the time frame for reporting to the CURES system to one working day.

Chairperson Lippe reported that the committee took a support position on AB 1752.

The board also expressed support for AB 1752. There were no comments from the public.

## **Committee Recommendation (Motion):** Support AB 1752.

Support: 10 Oppose: 0 Abstain: 0

<b>Board Member</b>	Support	Oppose	Abstain	Not Present
Brooks	х			
Butler	х			
Gutierrez	х			
Khan				х
Law	х			
Lippe	х			
Munoz	х			
Sanchez				Х
Schaad	х			
Veale	х			

Weisser	х		
Wong	х		

#### 4. AB 1753 (Low) Controlled Substances: CURES

Version: As introduced January 3, 2018

Status: Referred to Assembly Business and Professions Committee

**Summary**: This measure would limit the number of authorized security printers approved by the DOJ to three effective January 1, 2020. Further, this measure would require security forms to contain a unique serialized number that must be reported to CURES and would establish reporting requirements to the DOJ on the delivery of security forms to a prescriber.

Chairperson Lippe reported that during its January 2018 board meeting, the board discussed the issue of fraudulent security forms and how their use contributed to the opioid epidemic. After discussion, the board voted to pursue a statutory proposal to require e-prescribing while allowing for some exemptions.

Chairperson Lippe explained that this measure includes legislative findings regarding the use of paper prescription pads, including a finding that until mandatory e-prescribing is established, it is critical that tighter restrictions be placed on the manufacturing and tracking of prescription pads used within the state. He added that the board supports the transition to mandatory e-prescribing and will be pursuing legislation this year.

Chairperson Lippe stated that as AB 1753 appears to be consistent with the board's goals and provides for a transition period of enhanced accountability until an e-prescribing mandate can be implemented, the committee took a support position.

Ms. Herold stated that the goal is to move towards e-prescribing.

Mr. Law asked why the bill specifically limits the number of security printers to three. After discussion, the board asked staff to research how the author determined that three security printers are appropriate.

#### Committee Recommendation (Motion): Support AB 1753.

Support: 2 Oppose: 8 Abstain: 0

<b>Board Member</b>	Support	Oppose	Abstain	Not Present
Brooks		х		
Butler	х			
Gutierrez		Х		
Khan				х
Law		Х		
Lippe	х			
Munoz		Х		
Sanchez				х
Schaad		х		

Veale	Х	
Weisser	Х	
Wong	Х	

After voting down the committee's recommendation the board asked that staff work with the author to determine how the appropriate number of security printers was determined. Ms. Freedman added that once staff gathers the information the committee chair and board president can take a position on the bill.

#### 5. AB 710 (Wood) Cannabidiol

Version: As Amended January 18, 2018

**Status**: Referred to Senate Business, Professions and Economic Development

Committee

**Summary:** Would allow a product composed of cannabidiol to be prescribed or dispensed in accordance with federal law if the federal government excludes such products from the list of Schedule I items under the federal Controlled Substances Act.

Chairperson Lippe explained that this measure is similar to AB 845, which was introduced last year. He noted that the board established a neutral position on that measure.

Chairperson Lippe stated that as part of the board's action during its January 2018 board meeting, the board voted to pursue a statutory proposal to reconcile the variances between the state and federal controlled substances schedules.

Chairperson Lippe explained that based on counsel's review of this measure, it appears that some amendments may need to be offered to address a possible conflict between the two proposals, and therefore the committee did not take a position on AB 710.

Mr. Freeman explained that if AB 710 is passed the board will need to amend its bill to reconcile the variances between the state and federal controlled substances schedule. Mr. Room reported that legislative counsel has raised concerns with the board's proposal to reconcile the state and federal schedules. Ms. Herold stated that staff would continue to work with legislative counsel to address their concerns and move the bill forward.

Ms. Sodergren read the language of the AB 710 as provided below.

**11150.2.** (a) Notwithstanding any other law, if cannabidiol is excluded from Schedule I of the federal Controlled Substances Act and placed on a schedule of the act other than Schedule I, or if a product composed of cannabidiol is approved by the federal Food and Drug Administration and either placed on a schedule of the act other than Schedule I, or exempted from one or more provisions of the act, so as to permit a physician, pharmacist, or other authorized healing arts licensee acting within his or her scope of practice, to prescribe, furnish,

or dispense that product, the physician, pharmacist, or other authorized healing arts licensee who prescribes, furnishes, or dispenses that product in accordance with federal law shall be deemed to be in compliance with state law governing those acts.

Mr. Room clarified that while recreational use of cannabis has been approved in California, cannabidiol still cannot be prescribed.

Based on the discussion, the board decided to remain neutral on AB 710.

Motion: Remain neutral on AB 710.

M/S: Brooks/Lippe

Support: 9 Oppose: 1 Abstain: 0

<b>Board Member</b>	Support	Oppose	Abstain	Not Present
Brooks	х			
Butler	х			
Gutierrez	х			
Khan				х
Law	х			
Lippe	х			
Munoz	х			
Sanchez				Х
Schaad	х			
Veale	х			
Weisser		х		
Wong	х			

#### Part 2: Regulations for Discussion and Consideration

#### b. Board Adopted - Approved by the Office of Administrative Law

Chairperson Lippe briefly reviewed the following regulations that have been approved by the Office of Administrative Law.

- Regulations to Add Title 16 CCR Sections 1715.65, Related to the Inventory Reconciliation Report of Controlled Substances
- Regulations to Amend Title 16 CCR Sections 1760, Related to the Board's Disciplinary Guidelines
- Emergency Regulations to Amend Title 16 CCR Section 1735.2, Related to Compounding Beyond Use Dates

The board asked that staff notify licensees about the new regulations. Ms. Herold noted that this information would be provided in The Script.

There were no comments from the public.

Note: A copy of each adopted regulation text is posted on the board's website and can be obtained using the following link.

http://www.pharmacy.ca.gov/laws regs/pending regs.shtml

c. Board Adopted - Submitted for Administrative Review to the Department of Consumer Affairs or the Office of Administrative Law - Proposed Regulations to Amend Title 16 CCR Sections 1749, Related to the Board's Fees

Chairperson Lippe reported that the board currently has one regulation undergoing review by the Department or the Office of Administrative Law - the proposed regulations to amend Title 16 CCR section 1749 related to the board's free schedule.

Chairperson Lippe stated that the board meeting materials contain a summary of the regulation changes as well as the general timeline. He added that the board-adopted text is posted on the board's website and can be obtain using the following link. http://www.pharmacy.ca.gov/laws\_regs/pending\_regs.shtml

d. Board Approved to Initiate Rulemaking - Undergoing Pre-Notice Review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency, or Returned to Board Staff for Revisions Pursuant to Such Review:

Chairperson Lippe briefly reviewed the following regulations that are undergoing prenotice review.

- Proposed Regulations to Amend Title 16 CCR Sections 1780-1783, et seq., Related to Third-Party Logistics Providers and Dangerous Drug Distributors
- Proposed Regulations to Amend Title 16 CCR Section 1793.5, Related to the Pharmacy Technician Application, Section 1793.6 Related to the Pharmacy Technician Training Requirements and Section 1793.65 Related to the Pharmacy Technician Certification Programs
- Proposed Regulations to Amend Title 16 CCR Section 1707, Related to Offsite Storage
- Proposed Regulations to Amend Title 16 CCR Section 1746.3, Related to the Naloxone Fact Sheet
- Proposed Regulations to Amend Title 16 CCR Section 1709, Related to Pharmacy Ownership, Management, and Control, Including Through Trusts
- Proposed Regulations to Add Title 16 CCR Sections 1717.5, Related to Automatic Refill Programs
- Proposed Regulations to Amend Title 16 CCR Sections 1735.1, 1735.2, 1735.6,
   1751.1, and 1751.4, Related to Compounding

**Note:** The board meeting materials include a timeline for each of the proposed regulations as well as the board approved text.

There were no comments from the board or from the public.

e. Board Approved to Initiate Rulemaking – Board Staff Drafting Rulemaking
Documents for Pre-Notice Review by the Department of Consumer Affairs and the
Business, Consumer Services and Housing Agency

Chairperson Lippe briefly reviewed the following regulations that have been approved by the board to initiate rulemaking.

- Proposed Regulations to Amend Title 16 CCR Section 1735.2, Related to the Compounding Self-Assessment Form 17M-39
- Proposed Regulations to Amend Title 16 CCR Sections 1715 and 1784, Related to Pharmacy and Wholesaler Self-Assessment Forms 17M-13, 17M-14 and 17M-26

Note: The board meeting materials include a timeline for each of the proposed regulations as well as the board approved text.

There were no comments from the board or from the public.

#### **Part 3: General Committee Matters**

Chairperson Lippe provided the following committee meeting dates. He noted that the date for October will be changed as currently it is scheduled for a Saturday.

- April 24, 2018
- July 10, 2018
- October 20, 2018

The board recessed for a break at 1:03 p.m. and resumed at 1:43 p.m.

### IX. <u>Licensing Committee</u>

Chairperson Weisser provided a summary of the committee's efforts at the January 16, 2018, committee meeting.

 Discussion and Consideration of Proposed Creation of an Advanced Hospital Pharmacy Technician (AHT) Licensing Program including Licensure Requirements, Authorized Duties and Changes to Inpatient Pharmacy

Chairperson Weisser reported that at several meetings, the committee has discussed the creation of an advance pharmacy technician. Most recently, both the committee and subsequently the board voted to create separate license types for community pharmacy and hospital pharmacy. He added that during the meeting, the board also voted to pursue statutory changes to establish the requirements for the advanced community pharmacy technician.

Chairperson Weisser stated that during the January 16 committee meeting, members reviewed and discussed a proposal to create the advanced hospital pharmacy technician licensing program. The committee noted that the proposal is similar to the proposal developed and approved by the board for the advanced community

pharmacy technician licensing program.

Chairperson Weisser explained that the committee reviewed the draft statutory proposal including a definition, licensing requirements as well as authorized duties that are summarized below.

#### Definition

"Advanced Hospital Pharmacy Technician" means an individual licensed by the board who is authorized to perform technical pharmacy tasks as authorized in Section 4115.7.

#### **Licensing Requirements**

- Holds an active pharmacy technician license issued pursuant to this chapter that is in good standing.
- Possesses a certification issued by a pharmacy technician certifying program as defined in Section 4202(a)(4).
- Has obtained a minimum of an associate's degree in pharmacy technology, obtained a bachelor's degree, or higher or completed a board approved training program.
- Has obtained 3,000 hours of experience performing the duties of a licensed pharmacy technician in a hospital pharmacy.
- Has passed an advanced pharmacy technician examination.

In lieu of the requirements above, an individual who has graduated from a school of pharmacy recognized by the board would also be eligible for an AHT license.

#### **Renewal Requirements**

Completion of 20 hours of continuing education each renewal cycle.

#### **Proposed Duties**

In addition to the licensure requirements, the proposal establishes authorized duties an AHT could perform under the general direction of a pharmacist in a health care setting including:

- Packaging emergency supplies.
- Sealing emergency containers.
- Preparing and sealing drug kits.
- Performing unit inspections of drug supplies, as specified.
- Other duties deemed appropriate by the board.

# **Requirements for Hospital**

As a condition of using AHT personnel in a hospital, the proposal establishes obligations for the hospital, including:

- Policies and procedures that detail the duties that will be performed under the general direction of a pharmacist.
- PIC responsibility in the ongoing evaluation of the accuracy of the duties

- performed by the AHT.
- An electronic record that identifies AHT personnel responsible for performing the authorized duties.

Chairperson Weisser explained that as part of its deliberations, the committee reconsidered if the board should be creating a single advanced pharmacy technician licensing program that could be used in either the community or inpatient setting. The committee also considered if some of the advanced duties that could be performed in an inpatient setting would be also be appropriate for an advanced community pharmacy technician working in a closed-door pharmacy.

Chairperson Weisser reported that the committee made the following motion.

**Committee Recommendation (Motion):** Approve the draft language as provided during the meeting with the addition of language that would allow the board to modify the technical tasks via regulation and language that clarifies that the pharmacist is to be redirected to provide clinical services.

Ms. Sodergren explained that one of the key elements of this proposal is that the duties of an advanced hospital technician are now performed under the general direction of the pharmacist rather than under the direct supervision of the pharmacist.

Ms. Sodergren read the definition of "direct supervision" from Business and Professions Code section 4023.5 as follows.

4023.5. Direct Supervision and Control

For the purposes of this chapter, "direct supervision and control" means that a pharmacist is on the premises at all times and is fully aware of all activities performed by either a pharmacy technician or intern pharmacist.

President Gutierrez recommended that the committee consider combining the tech-check-tech requirements into this regulation. Ms. Veale noted that tech-check-tech is included in the proposed language in 4115.7 (a)(5). However, she recommended that the language be modified to clarify that it is allowing a pharmacy technician to check the work of another technician per 1793.8.

President Gutierrez recommended modifying 4115.7(a)(5) to read as follows. The board agreed with her recommendation.

4115.7(a)(5) Verify the accuracy of a pharmacy technician's filling of floor and ward stock and unit dose distribution systems for hospital <u>patient</u> orders that have been previously reviewed and approved by a licensed pharmacist.

Mr. Law expressed concern that 3,000 hours of experience are not enough to qualify someone as an advanced pharmacy technician. Mr. Weisser explained that in addition to 3,000 hours of experience hours the technician also must meet educational

requirements and pass an exam prior to being eligible for licensure as an AHT.

Mr. Brooks asked how much additional pay an AHT will receive. The board responded that this would be determined by the marketplace.

After discussion, the board determined that based on the duties completed by an advanced hospital technician, 3,000 hours of experience is appropriate.

Dr. Wong expressed his concern that pharmacists may feel pressured by their employer to use AHTs even if the pharmacist does not feel it is safe or appropriate. Ms. Veale commented that the board does not mandate the use of an AHT and the PIC is ultimately responsible to ensure that they are used appropriately.

Pat Whalen representing the United Nurses Association of California/Union of Healthcare Professionals stated that the union is opposed to this proposal. He explained that UNAC/UHCP represents over 30,000 registered nurses and other health care professionals, including optometrists; pharmacists; physical, occupational and speech therapists; case managers; nurse midwives; social workers; clinical lab scientists; physician assistants and nurse practitioners.

Mr. Whalen explained that UNAC/UHCP opposes the language because it is bad for patient health, pharmacists and the public. Mr. Whalen stated that stakeholder meetings were held with Senator Hernandez regarding the advanced community pharmacy technician. He stated that during this meeting it was apparent that chain drug stores supported the idea of advanced technicians, but in practice they wouldn't actually use them unless they are exempted from ratios.

Chairperson Weisser stated that the committee has not focused on how advanced technicians may change the business models for pharmacies; they have focused on how California patients will benefit from interacting more with their pharmacist.

Ms. Butler expressed concern with pharmacists having to oversee too many staff in a pharmacy.

Mr. Whalen stated that SEIU is against the proposal for advanced pharmacy technicians because the barriers to entry are too high.

Note: Ms. Munoz left the room at 2:20 p.m. and returned at 2:30 p.m.

Missy Johnson representing the California Pharmacist Association clarified that CPhA is supportive of advanced pharmacy technicians in theory. She stated that CPhA is focusing on getting advanced pharmacists reimbursed for their services because without this reimbursement they will not have money to use advanced pharmacy technicians. She further clarified that CPhA does not have a position on either the advanced community pharmacy technician or the advanced hospital technician proposals.

Two pharmacy technicians stated that they would not support requiring two separate exams for either working in a hospital or community pharmacy they also spoke against

requiring an AA degree.

A member of the public stated that the board should consider holding the owner or the corporation responsible for work completed by advanced pharmacy technicians so that they will not force pharmacists to use advanced technicians in an unsafe manner. Ms. Herold stated that part of the proposal includes that the advanced technician shares responsibly for their actions with the pharmacist.

Mark Johnson stated that CVS Health is committed to advanced health care because it benefits public health.

**Committee Recommendation (Motion):** Approve the draft language as provided below with the addition of language that would allow the board to modify the technical tasks via regulation, language that clarifies that the pharmacist is to be redirected to provide clinical services, and the modification of 4115.7(a)(5) to read "hospital patient orders".

### Proposed BPC 4038.6

"Advanced Hospital Pharmacy Technician" means an individual licensed by the board who is authorized to perform technical pharmacy tasks as authorized in Section 4115.7.

#### Proposed 4115.7

- (a) In a hospital pharmacy, licensed advanced hospital pharmacy technician may perform the nondiscretionary tasks authorized in Section 4115 in addition to the following technical tasks under the general direction of a pharmacist:
  - (1) Package emergency supplies for use in the health care facility.
  - (2) Seal emergency containers for use in health care facility.
  - (3) Prepare and seal drug kits for use in the health care facility.
  - (4) Perform unit inspections of the drug supplies stored throughout the health care facility. Irregularities shall be reported within 24 hours to the pharmacist-in-charge and the director or chief executive officer of the health facility in accordance with the health care facility's policies and procedures.
  - (5) Verify the accuracy of a pharmacy technician's filling of floor and ward stock and unit dose distribution systems for hospital <u>patient</u> orders that have been previously reviewed and approved by a licensed pharmacist.
  - (6) Other technical tasks deemed appropriate by the board.
- (b) A hospital pharmacy may use the services of an advanced hospital pharmacy technician if all of the following conditions are met:
  - (1) The duties authorized in (a) are performed under general direction of a pharmacist and are specified in the hospital pharmacy's policies and procedures
  - (2) The pharmacist-in-charge is responsible for ongoing evaluation of the performance of personnel as authorized in subdivision (a).
  - (3) Pharmacists are deployed to the inpatient care setting to provide clinical services.

#### Proposed BCP 4211.1

(a) The board may issue an advanced hospital pharmacy technician license to an

individual who meets all the following requirements:

- (1) Holds an active pharmacy technician license issued pursuant to this chapter that is in good standing,
- (2) Possesses a certification issued by a pharmacy technician certifying program as defined in Section 4202(a)(4).
- (3) Has obtained a minimum of an associate's degree in pharmacy technology, obtained a bachelor's degree, or higher or completed a board-approved training program.
- (4) Has obtained 3,000 hours of experience performing the duties of a licensed pharmacy technician in a hospital pharmacy.
- (5) Has passed an advanced pharmacy technician examination.
- (b) As an alternative to the requirements in subdivision (a), the applicant has graduated from a school of pharmacy recognized by the board.
- (a) A license issued pursuant to this section shall be valid for two years.
- (b) Each person, upon application for licensure, shall pay to the executive officer of the board the fees provided by this chapter. The fees shall be compensation to the board for investigation or examination of the applicant.

#### Proposed BPC 4234.5

An advanced hospital pharmacy technician shall complete 20 hours of continuing education each renewal cycle. A licensee must also maintain certification as specified in Section 4211.1 (a)(2).

# Proposal to Amend BPC 4400

...

(z) This section shall become operative on July 1, 2017. The fee for the advanced hospital pharmacy technician application and examination shall be \$260 dollars and may be increased to \$285. The fee for initial licensure and biennial renewal of as an advanced hospital pharmacy technician shall be \$140 and may be increased to \$195.

Support: 7 Oppose: 2 Abstain: 1

<b>Board Member</b>	Support	Oppose	Abstain	Not Present
Brooks		х		
Butler	х			
Gutierrez	х			
Khan				Х
Law		х		
Lippe	х			
Munoz			х	
Sanchez				Х
Schaad	х			
Veale	х			
Weisser	х			
Wong	х			

 Discussion and Consideration of Regulations Pursuant to Assembly Bill 401 (Chapter 548, Statutes of 2017) Relating to Pharmacy Technicians Working in a Remote Dispensing Site Pharmacy Chairperson Weisser explained that last year the governor signed AB 401, which among other changes, created a remote dispensing site pharmacy (RDSP) licensing program under the board's jurisdiction. As part of the regulatory framework established by the legislation, the board is required to develop regulations that shall apply to pharmacy technicians working at an RDSP [BPC 4132(a)].

Ms. Sodergren briefly reviewed the requirements for an RDSP as outlined in AB 401.

Chairperson Weisser reported that during the January 16 meeting, the committee discussed the basic framework for a regulation to create the requirements that an RDSP must meet in order to work in a remote dispensing site pharmacy.

Chairperson Weisser stated that as part of its discussion the committee noted that the policy on the creation of an RDSP has already been decided and that now the board's obligation is to implement the provisions as required. The committee discussed the approved duties for the technicians working at the remote dispensing pharmacy which include performing order entry, packaging, manipulative, repetitive, and other nondiscretionary tasks at a remote dispensing site pharmacy under the supervision of a pharmacist at a supervising pharmacy using a telepharmacy system.

Chairperson Weisser explained that under the new provisions of an RDSP, dangerous drugs and devices and controlled substances may be ordered by a remote dispensing site pharmacy licensed by the board and may be signed for and received by a registered pharmacy technician at the remote site. However, a controlled substance signed for by a pharmacy technician must be stored separately from existing inventory until the controlled substance is reviewed and countersigned by a pharmacist. He added that any receipt and storage of a controlled substance by a pharmacy technician must be captured on video and maintained by the remote dispensing site pharmacy for 120 days.

Chairperson Weisser reported that the committee initially considered a proposal that would have established requirements similar to that the proposed advanced community pharmacy technician but the committee determined that given the scope of duties and supervision of a pharmacist, the regulation requirements could be lessened.

Chairperson Weisser stated that the committee made the following motion.

**Committee Recommendation (Motion):** Direct staff to develop draft regulation language for a pharmacy technician working in a remote dispensing site pharmacy to include the following requirements:

- 1. Have a pharmacy technician license that is in good standing.
- 2. Possess and maintain a certification issued by a pharmacy technician certifying program.
- 3. Possesses a minimum of an AA degree pharmacy technology, bachelor's degree (or higher), or has completed a board approved training program.
- 4. Complete 1,000 hours of pharmacy technician experience within the last

three years.

Mr. Weisser explained that since the committee meeting staff drafted regulation language as directed by the committee. He noted that the language was provided in the board meeting materials for review by the board and the public.

Mr. Law and Ms. Butler expressed concern that 1,000 hours of experience is not enough to qualify a technician to work in an RDSP. Ms. Veale stated that it is up to the PIC and the pharmacy to hire a qualified person whom they trust to work in the RDSP.

The board asked if an RDSP would need to close if a traditional pharmacy moved into the area. Ms. Johnson clarified that section 4130(c)(2) allows the RDSP to continue to operate even if another pharmacy moves into the medically underserved area.

Ms. Butler asked how many pharmacy technicians can work in a RDSP. Ms. Johnson stated that two pharmacy technicians can work in the RDSP. She explained that they did that to comply with employment law (i.e. lunch breaks).

Ms. Munoz stated that while she supports providing more access to health care, she is abstaining from the vote because there are different requirements for advanced pharmacy technicians vs. technicians working in an RDSP.

Ms. Veale explained that the committee determined that because technicians in an RDSP cannot complete the same tasks as an advanced technician (i.e. immunizations, tech-check-tech, taking orders over the phone, etc.) the requirements did not need to be as high.

Ms. Johnson stated that other states that use telepharmacy technology have experience hour requirements ranging from 500 to 2,500 hours.

A pharmacist expressed concern with pharmacists not being able to fulfil the duties in their pharmacy while overseeing two pharmacy technicians in a remote pharmacy.

Note: Mr. Wong left the room at 3:52 p.m. and was not present for the vote.

**Committee Recommendation (Motion):** Approve the draft regulation language for a pharmacy technician working in a remote dispensing site pharmacy as follows.

Add section 1793.9 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1793.9 Pharmacy Technician in a Remote Dispensing Site Pharmacy

A pharmacy technician must satisfy each of the following requirements before working in a remote dispensing site pharmacy:

- (a) Possess a pharmacy technician license that is in good standing.
- (b) Possess and maintain a certification issued by an approved pharmacy technician certifying program.
- (c) (1) Possess a minimum of an associate's degree in pharmacy technology or a

bachelor's degree in any subject, or (2) complete a board approved training program. (d) Complete 1,000 hours of experience working as a pharmacy technician within the three years prior to first working in the remote dispensing site pharmacy.

Authority: Section 4005 and 4132, Business and Professions Code

Reference: 4005, 4026.5, 4044.3, 4052.1, 4115, 4132, and 4202, Business and

**Professions Code** 

Support: 5 Oppose: 2 Abstain: 2

Board Member	Support	Oppose	Abstain	Not Present
Brooks	х			
Butler		х		
Gutierrez			х	
Khan				х
Law		х		
Lippe	х			
Munoz			х	
Sanchez				х
Schaad	х			
Veale	х			
Weisser	х			
Wong				х

**Motion:** Approve the proposed addition to Title 16 CCR Section 1793.9 and initiate the formal rulemaking process. Further, delegate to the executive officer the authority to make any non-substantive changes and clarifying changes consistent with the board's policy direction upon recommendations of the control agencies.

M/S: Brooks/Veale

Support: 6 Oppose: 2 Abstain: 1

<b>Board Member</b>	Support	Oppose	Abstain	Not Present
Brooks	х			
Butler		х		
Gutierrez	х			
Khan				Х
Law		х		
Lippe	х			
Munoz			х	
Sanchez				х
Schaad	х			
Veale	х			
Weisser	х	-		
Wong				X

c. Discussion and Consideration of the Title 16, California Code of Regulations, Section 1706.2, Related to Abandonment of Application Files Licensing Statistics

Chairperson Weisser explained that CCR Section 1706.2 establishes the provisions under which the board may determine an application is abandoned. Without this regulatory section, applicants would not understand the criteria used by board staff to deem an application abandoned, which results in an application being withdrawn.

Chairperson Weisser reported that the committee noted during the January 16 meeting that as the board's regulatory jurisdiction continues to grow, this regulation requires frequent amendments to incorporate each newly created licensing program. He explained that in its current form, the regulation specifically mentions each license type (i.e. pharmacist, pharmacy technician, wholesaler, pharmacy, etc.).

Chairperson Weisser stated that the committee considered a recommendation offered by board staff to simplify the language to consolidate licenses issued to a premise as well as the licenses issued to individuals.

Chairperson Weisser reported that the committee discussed that such an approach will ensure that all applicants have appropriate notice about the requirements for abandoning an application, while reducing the administrative workload associated with frequent amendments to the regulation.

Chairperson Weisser stated that the committee made the following motion.

**Committee Recommendation (Motion):** Approve the language as provided in the meeting materials to amend CCR Section 1706.2.

The board agreed with the committee recommendation and there were no comments from the public.

**Committee Recommendation (Motion):** Approve the language as provided in the meeting materials to amend CCR Section 1706.2.

Support: 10 Oppose: 0 Abstain: 0

<b>Board Member</b>	Support	Oppose	Abstain	Not Present
Brooks	х			
Butler	х			
Gutierrez	х			
Khan				х
Law	х			
Lippe	х			
Munoz	х			
Sanchez				Х
Schaad	х			
Veale	х			
Weisser	х			
Wong	х			

Motion: Approve the proposed amendment to Title 16 CCR Section 1706.2 and initiate

the formal rulemaking process. Further, delegate to the executive officer the authority to make any non-substantive changes and clarifying changes consistent with the board's policy direction upon recommendations of the control agencies.

M/S: Veale/Gutierrez

Support: 10 Oppose: 0 Abstain: 0

<b>Board Member</b>	Support	Oppose	Abstain	Not Present
Brooks	х			
Butler	х			
Gutierrez	х			
Khan				х
Law	х			
Lippe	х			
Munoz	х			
Sanchez				х
Schaad	х			
Veale	х			
Weisser	х			
Wong	х			

# d. Discussion and Consideration of Patient Consultation Requirements for Mail Order Pharmacies or Nonresident Pharmacies

Chairperson Weisser explained that BPC section 4112 establishes the licensing requirements for a nonresident pharmacy. Further, as part of this section, Subdivision (h) requires the board adopt regulations that apply the same requirements for oral consultation for medications dispensed for such pharmacies.

Chairperson Weisser noted that CCR section 1707.2 establishes the duty of a pharmacist to provide oral consultations to his or her patient in all care settings under specified conditions.

Chairperson Weisser reported that at the January 16 meeting the committee discussed consultation requirements for nonresident pharmacies and other mail order pharmacies. As part of its discussion the committee considered:

- Are the current requirements for mail order and nonresident pharmacies sufficient to ensure patients have access to a pharmacist for consultation?
- How can mail order and nonresident patients be advised that they have the right to translation services? Are existing requirements sufficient?
- Are patients of mail order and nonresident pharmacies receiving appropriate consultation?
- Does the board need to treat mail order pharmacies and nonresident pharmacies differently if they both ship medication to patients?
- Should the board promulgate regulations for nonresident pharmacies consistent with the provisions of Business and Professions Code section 4112(h)?

Chairperson Weisser stated that the committee discussed the number of complaints the board receives each year involving mail order pharmacies and how patients are advised of their right to have translation services available. The committee also heard from representatives of mail order pharmacies that detailed their business models and how their respective companies provide oral consultation.

Chairperson Weisser reported that the committee made the following motion.

**Committee Recommendation (Motion)**: Direct staff to amend CCR Section 1707.2(b)(1) and 1707.2(b)(2)(B) as follows:

...

**1707.2(b)(1)** In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in which the patient or agent is present:

•••

1707.2 (b)(2)(B) a telephone number shall be provided to the patient from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record. The pharmacists shall be available to speak to the patient no less than six days per week, and for a minimum of 40 hours per week and the call shall be answered by a pharmacist within two minutes.;

Chairperson Weisser stated that the committee also directed staff to draft proposed language requiring patient notification of the availability of translation services and patient notification of how to file a complaint with the board of pharmacy.

President Gutierrez asked how the committee determined that calls shall be answered by a pharmacist within two minutes. Mr. Weisser stated that the committee wanted to ensure that patients are able to reach a pharmacist quickly. President Gutierrez stated that even when a patient calls a regular pharmacy she or she experiences a long wait time, and she recommended removing a time frame.

Ms. Veale stated that as written the language would apply not only to mail order pharmacies - it would apply to *all* pharmacy settings.

The board discussed modifying the language to say that a pharmacist must be available during normal business hours.

Mr. Weisser asked if the board wants to address the fact that patients are on hold for long periods of time without being able to speak to a pharmacist. President Gutierrez stated that consumers can file a complaint with the board.

Mr. Herold explained that she recently called a mail order pharmacy and was unable to speak to a pharmacist. She added that the board received complaints from patients whose therapy was delayed because they could not speak to a pharmacist.

President Gutierrez recommended that the board require that mail order pharmacies

provide notice to patients that a pharmacist is available during normal business hours.

Ms. Freedman read Business and Professions Code section 4112(f) as follows and explained that the requirements in the section only apply to pharmacies located outside of California.

**4112(f):** Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. This toll-free telephone number shall be disclosed on a label affixed to each container of drugs dispensed to patients in this state.

Mr. Brooks asked if the board had any authority to discipline a mail order pharmacy for keeping a patient on hold too long before they can talk to a pharmacist. Mr. Herold responded that currently there is no law that the board could use to discipline a mail order pharmacy for having a patient on hold for too long.

Ms. Veale stated that she has seen reports that show that mail order pharmacy enrollment is not increasing, but remaining flat. She added that the quality of patient care provided by mail order pharmacies has improved over the years.

Dr. Wong stated that he would like there to be a direct phone number for patients to reach a pharmacist immediately.

Ms. Veale stated that the committee needs to be mindful that these new requirements could also apply to other pharmacy settings.

President Gutierrez recommended that the committee discuss the issue again and look at how other states regulate mail order pharmacies.

The board asked the committee to discuss how long a patient should have to wait to talk to a pharmacist and how the board could enforce a timing requirement.

The board also asked that the committee discuss the possibility of requiring the mail order pharmacy to proactively reach out the patients to provide a consultation for all new or modified prescriptions.

# e. Update on Implementation of Board-Provided Law and Ethics Continuing Education Courses

Chairperson Weisser explained that CCR section 1732.5 establishes the renewal requirements for pharmacists including a provision that requires, effective July 1, 2019, all pharmacists renewing their licenses must have obtained at least two hours of continuing education on pharmacy law and ethics.

Chairperson Weisser reported that the committee was advised of the efforts underway to develop a webinar that pharmacists can complete to comply with section

1732.5(b). The webinar will highlight new pharmacy law taking effect 1/1/18. He noted that the course will include a brief introduction by the board president, and the executive officer will provide the presentation of new laws and ethics.

Board staff reported that the webinar should be completed by the end of March for deployment.

There were no comments from the public or from the board.

#### f. Future Committee Meeting Dates

Chairperson Weisser announced the following committee meeting dates.

- April 19, 2018
- June 26, 2018
- September 26, 2018

The board recessed to closed session at 4:45 p.m.

#### Wednesday, February 7, 2018

President Gutierrez returned the meeting to open session at 9:04 a.m.

Board members present: Gregory Lippe, Allen Schaad, Ryan Brooks, Stanley Weisser, Valerie Munoz, Victor Law, Amy Gutierrez, Deborah Veale and Albert Wong.

The board honored Susan Capello for 25 years of state service and Joey Paman for 35 years of state service.

#### X. Communication and Public Education Committee

Vice chairperson Deborah Veale presented a summary of the committee's efforts at the January 31, 2018, committee meeting

# a. Summary of Presentation Regarding Prescription Drug Overdose Prevention and Corresponding Responsibility

Ms. Veale reported that at the committee meeting former board member Ramón Castellblanch presented information about the growing number of opioid deaths from overdoses and the effectiveness of naloxone in reversing overdoses. He said pharmacy board websites can be valuable educational tools for stopping overdoses and offered a sample from the Kentucky Board of Pharmacy website. The Kentucky website features a prominent box on the homepage that links directly to a separate website dedicated to opioid overdose prevention.

Ms. Veale explained that during the committee meeting Dr. Castellblanch also said he found confusion among California pharmacists about what corresponding responsibility is, about how to use CURES and about calculating morphine equivalents.

He said some states require CE about the opioid epidemic for pharmacists, including lowa, Florida and Oregon. He said more needs to be done to educate pharmacists about the opioid epidemic.

Note: A copy of Dr. Castellblanch's presentation was provided in the meeting materials.

Ms. Herold reported that the board has provided training on naloxone and corresponding responsibility to about 700 pharmacists at CE seminars cosponsored with the DEA around the state. She added that the committee would be considering a CE webinar on naloxone for the board's website later in the meeting.

The board expressed its support for the naloxone and corresponding responsibility training.

The committee discussed the importance of educating pharmacists about naloxone and "red flags." Members directed staff to explore ways to make information about naloxone and "red flags" more visible on the website, including a main button on the homepage that links directly to the information on the website.

# b. Discussion and Consideration of a Proposal for a Public Service Billboard Message and Related Communications Materials on Drug Abuse

Ms. Veale reported that at the November 2017 board meeting, the board considered several possible messages presented by the Communication and Public Education Committee for a billboard about drug abuse prevention. She added that the board directed the committee chairperson and executive officer to make the final selection and to work on the project with Mr. Brooks' firm, Outfront Media, which has agreed to donate five billboards for the project.

Ms. Veale stated that the chairperson and executive officer chose "Use, Don't Abuse" for the billboard message. In addition, the chairperson and executive officer selected a final overall design for the billboard – including the message, artwork and the Board of Pharmacy logo and website.

Note: A copy of the final billboard design was provided in the board meeting materials.

Public Information Officer Bob Davila explained that prescription drug abuse information on the board's website is being revamped with a fresh look and updated resources. The billboard will be featured prominently on the homepage and will serve as a link to a separate webpage dedicated to information about drug abuse and where to dispose of unused medications.

Mr. Davila reported that the billboard design is being prepared for submission to Outfront Media. He added that the plan is to have the new webpage up and running before the billboards are erected, with a goal of completion this spring.

Mr. Lippe asked why the board's website information is not shown more prominently on the billboard. Ms. Veale and Mr. Brooks explained that the message of the billboard is focused on prescription drug abuse, rather than promoting the Board of Pharmacy.

The board thanked Mr. Brooks for donating billboard space to the board for this important consumer protection campaign.

c. Discussion and Consideration of Possible Options for Consumer and Pharmacist Education Regarding Safe Medication Transitions for Patients upon Discharge from Health Care Facilities and Any Necessary Statutory or Regulatory Changes

Ms. Veale explained that at the July 2017 board meeting, the board directed the committee to discuss developing materials to educate consumers and pharmacists about the importance of having a patient medication history on hand when being admitted to a hospital. The board also asked staff to develop public outreach materials on this topic for the website.

Ms. Veale stated that at the September 2017 Communication and Public Education Committee meeting, the committee discussed possibly developing a phone app for storing medication history. However, it was noted that such apps already exist.

Ms. Veale reported that at the January 31 meeting the committee received printed information provided by Rita Shane, Pharm.D.; and a January 2018 article from U.S. News and World Report, "9 Strategies for Reducing Emergency Room Medication Errors."

Ms. Veale explained that the committee discussed how to convey information about safe medication transitions to two distinct audiences – consumers and pharmacists. The committee directed staff to explore ways to inform consumers about compiling and carrying a current medication inventory through various media, including the board's website and the DCA's blog, publications and social media accounts.

Ms. Veale also reported that the committee directed staff to produce a *Script* article about the role of pharmacists in reducing medication errors during patient stays in hospitals. She noted that members suggested sharing the *Script* article with other healing arts boards to share with their licensees.

Ms. Veale stated that the committee also discussed reaching out to pharmacy schools to ask if their curriculum includes training related to safe medication transitions. The committee also heard comments from an Oakland community pharmacist who said his pharmacy is starting a project with Alameda Health System to be a part of the hospital's care transition program.

Mr. Davila stated that board staff is working on the educational materials for both consumers and medical professionals. Ms. Herold added that this is very important information for consumers. President Gutierrez recommended working with hospital associations to educate their employees.

There were no comments from the public.

# d. Discussion and Consideration of Educational Materials Regarding Drug Take-Back Collection Receptacles and Providing Public Access to Such Information

Ms. Veale reported that at the July 2017 board meeting, the board directed the committee to develop consumer information on accessing drug take-back programs.

Ms. Veale stated that at the January 31 committee meeting staff reported that forms to report installing or discontinuing a collection receptacle and to report tampering, damage or theft of a receptacle are now posted on the board's website. It was also noted that an announcement about the forms was posted on the website and was sent directly to pharmacies in a subscriber alert.

Ms. Veale explained that the registration forms will be used to develop an online locator that consumers can use to find drug take-back programs. She noted that the goal is to develop easy-to-find consumer information about take-back programs on the board's website.

Mr. Davila reported that to date approximately 160 registration application forms have been received. He added that eventually pharmacies will be able to complete the registration form online.

Mr. Davila presented the board with the drug-take back search webpage, which was in the final stages of development. He showed the board how consumers could search for take-back locations using city, zip code or pharmacy name.

The board was pleased with the search page and thanked Mr. Davila and Victor Perez for their work on its development.

Ms. Veale asked if the page will display other drug take back locations, such as police stations. Mr. Davila responded that the goal is to eventually have the webpage display search results for take-back locations from other agencies as well as the board's licensees.

Dr. Wong stated that he has a take-back bin in his pharmacy and his patients are very grateful that it is available to them. He noted that the bin has to be emptied every two weeks because it fills up so quickly.

Dr. Wong asked if the board will be working to develop take-back requirements for sharps as his patients are always asking how they can safely dispose of their used needles. Ms. Herold responded that this is a significant problem for patients and some counties have created mandates for sharps disposal. Mr. Davila stated that the board could add links to organizations such as Cal Recycle that can safely dispose of used sharps.

President Gutierrez asked staff to gather information on how many of the take-back bins are located in counties that provide funding to pharmacies to host them. Dr. Wong noted that his bin is county funded.

There were no comments from the public.

# e. Discussion and Consideration of Creating Webinar Course to Satisfy Education Requirement for Pharmacists to Furnish Naloxone

Ms. Veale explained that SB 493 authorized the board to address the problem of restricted public access to naloxone, which reverses opioid overdose. The board responded in 2015 with an emergency regulation in 2015 and a permanent regulation in 2016 establishing a protocol for pharmacists to furnish naloxone without a prescription.

Ms. Veale reported that the board also has taken steps to assist pharmacists in taking advantage of the naloxone protocol. Last year, the board and the U.S. Drug Enforcement Administration (DEA) cohosted training sessions for pharmacists throughout the state that included one hour of CE credit to meet the education requirement of the naloxone protocol.

Ms. Veale stated that at its January 31 meeting the committee discussed approval of a proposed webinar course to satisfy the one-hour CE requirement for furnishing naloxone. The course was developed by Talia Puzantian, Pharm.D., of Keck Graduate Institute School of Pharmacy and James J. Gasper, Pharm.D., California Department of Health Care Services.

Note: A copy of the webinar course is provided in the board meeting materials.

Ms. Veale explained that at the committee meeting Dr. Gasper reported that the course material has been well received by pharmacists in several rural counties where it has been presented in person.

Ms. Veale reported that the committee was impressed with the course presented by Dr. Gasper and determined that it could be turned into a webinar available on the board's website for pharmacists to complete the one hour of CE credit required to provide naloxone.

Ms. Herold reported that approximately 700 pharmacists have become certified to provide naloxone by attending the in-person training provided by the board and the DEA. She added that there are other avenues available for pharmacists to become certified.

Ms. Veale explained that the committee felt that the webinar would be a way to get pharmacists certified even if they are not able to attend an in-person training and made the following motion.

**Committee recommendation:** Create a webinar course using the materials presented by Dr. Gasper to satisfy the education requirements for pharmacists to furnish naloxone.

Mr. Weisser stated that all pharmacists should become certified so they can provide naloxone to their patients.

Board staff stated that they would work with the Department's Solid Training unit to develop the naloxone webinar that would provide the pharmacist with proof of completion and certification in naloxone.

Ms. Veale stated that the committee will be looking at ways to encourage pharmacists to use their education to proactively talk to their patients about naloxone. Ms. Herold added that a member of the Legislature is interested in creating a requirement to have specialized consultations for opioid prescriptions, which would include information on naloxone.

The board expressed interest in working with the Medical Board to find ways to educate patients on naloxone when the doctor prescribes the opioid as well as when they pick up their prescription at the pharmacy.

Dr. Wong stated that the board should consider developing educational materials on naloxone that pharmacists could display in their pharmacy.

President Gutierrez asked if a remote telepharmacy location could provide naloxone. Ms. Herold explained that the pharmacist would provide the patient consultation via video and the patient could then receive the naloxone.

Mr. Brooks asked if schools are allowed to provide naloxone. Ms. Sodergren explained that Business and Professions Code section 4119.8 allows a pharmacy to furnish naloxone to a school district, county office of education, or charter school. She added that it can be administered by school staff, including non-healthcare professionals.

The board asked that the committee discuss ways to educate schools on how pharmacists can help them obtain naloxone and train them to use it.

Daniel Martinez stated that CPhA provides naloxone training courses. He added that they are working to get pharmacists reimbursed under MediCal for providing naloxone services.

Ms. Veale explained to the board that MediCal and insurance companies will pay for the naloxone, but they will not reimburse for the pharmacist's consultation.

The board discussed the pricing of the various formularies of naloxone.

Paige Talley commented that for some insurance companies the consultation fee is \$25 and the co-pay is \$30. She noted that without insurance the nasal spray naloxone is approximately \$150 and the injectable is approximately \$50.

**Committee Recommendation (Motion):** Create a webinar course using the materials presented by Dr. Gasper to satisfy the education requirements for pharmacists to furnish naloxone.

Support: 9 Oppose: 0 Abstain: 0

<b>Board Member</b>	Support	Oppose	Abstain	Not Present
Brooks	х			
Butler				х
Gutierrez	х			
Khan				х
Law	х			
Lippe	х			
Munoz	х			
Sanchez				Х
Schaad	х			
Veale	х			
Weisser	х	-		
Wong	х			

# f. Discussion and Consideration of UC Berkeley Study of the Availability of Contraception Prescribed by Pharmacists in California

Ms. Veale explained that SB 493 authorized California pharmacies to dispense hormonal contraception without a prescription. The board adopted a protocol for pharmacists to furnish self-administered hormonal contraception without a prescription in April 2016.

Ms. Veale reported that the committee received a copy of a UC Berkeley study published in the *Journal of the American Medical Association* in December 2017 that reported only 11 percent of California pharmacies are dispensing hormonal contraception to women without a prescription.

Note: A copy of the UC Berkeley study was provided in the board meeting materials.

Ms. Veale stated that the study was based on a survey of pharmacies between February 2017 and April 2017. The study identified several barriers to implementation of the contraception portion of SB 493, including pharmacists' concerns about training, liability, staffing and lack of reimbursement.

Ms. Veale reported that the committee thanked staff for the information and took no action.

Mr. Weisser stated that he is disappointed that more pharmacists are not providing hormonal contraception for their patients.

President Gutierrez asked if the study showed that women are simply choosing to go to their doctor to obtain contraception. Ms. Veale stated that pharmacies near college campuses or in medically underserved areas are more likely to have patients requesting contraception.

President Gutierrez asked if a remote telepharmacy could provide contraception. Ms. Herold confirmed that it could.

Daniel Martinez stated that CPhA is not only providing training courses on contraception, they are also working to get pharmacists reimbursed for providing the services.

Mark Johnson, representing CVS Health, reported that on July 1, 2018, pharmacists in Idaho will have prescriptive authority to prescribe in 31 different categories of drugs, which will help make pharmacies health care centers.

Mr. Weisser asked why Idaho passed this law. Mr. Johnson explained that in Idaho there is a shortage of doctors and this is intended to preclude or prevent doctors from having to see patients for common, minor ailments such as strep throat. The board spoke in support of increasing health care access.

# g. Discussion and Consideration of FDA Proposal to Increase Consumer Protection from High-Risk Homeopathic Drugs

Ms. Veale explained that in December 2017, the Food and Drug Administration (FDA) announced plans to change the way it regulates homeopathic drugs to a new approach based on potential risk to patients. The FDA said the new policy will focus on enforcement and regulation of homeopathic drugs that pose the greatest risk to patients. Ms. Veale stated that the FDA said its regulatory policy for homeopathic drug products has not been updated since 1988. Since then, homeopathic drugs have grown from a small market to a \$3 billion industry.

Note: Copies of the FDA news release and an FDA draft guidance are provided in the board meeting materials.

Ms. Veale stated that during its meeting the committee noted that many homeopathic drugs are actually home remedies used in immigrant communities and imported from other countries. Committee members also noted that some of these remedies may have ingredients that are actually harmful to patients, and they should be monitored and regulated by the FDA.

Ms. Veale reported that the FDA has begun issuing more recalls of homeopathic products. She also reported that the committee recommended sending out more subscriber alerts about recalls of these products because many pharmacy chains carry sections of homeopathic drugs.

Ms. Veale explained that the committee agreed to continue monitoring FDA activities in this area before considering whether board action is warranted.

There were no comments from the board or from the public.

# h. Discussion and Consideration of FDA Guidance, "Evaluating Drug Effects on the Ability to Operate a Motor Vehicle"

Ms. Veale explained that in April 2017, the board amended Title 16, California Code of Regulations section 1744, to require that pharmacists include a written label on

prescription drug containers warning the drug may impair a person's ability to operate a vehicle or vessel. The regulation identifies specific classes of drugs that may impair a person's ability to drive a vehicle or vessel. The regulation also requires pharmacists to add a written warning to the container of any drug that, based on a pharmacist's professional judgment, may impair a person's ability to operate a vehicle or vessel.

Ms. Veale reported that at the January 31 meeting the committee received a copy of FDA guidance, "Evaluating Drug Effects on the Ability to Operate a Motor Vehicle," issued in November 2017. The guidance notes the importance of preventing motor vehicle accidents that result from drug-impaired driving and the need for drug manufacturers to evaluate the effect of a drug on driving ability.

Ms. Veale explained that the committee discussed whether California's regulation needs additional amendment based on the FDA's guidance. The committee agreed that section 1744 is comprehensive and needs no amendment.

There were no comments from the board or from the public.

 Discussion and Consideration of Journal of the American Pharmacists Association Article, "Enhancing the Educational Value of Direct-to-Consumer Advertising of Prescription Drugs"

Ms. Veale reported that a study in the September/October 2017 issue of the Journal of American Pharmacists Association looked at how well consumers understand and retain information about the benefits and risks of a prescription drug that is conveyed in direct-to-consumer advertising (DTCA) by pharmaceutical companies.

Ms. Veale explained that the study compared an original print DTCA with an ad modified by health literacy principles. The modified ad avoided medical terms and used simple plain language, short paragraphs and sentences, and active verbs. The modified ad also was printed in at least 12-point font with information written at or below eighth-grade reading level.

Ms. Veale stated that researchers found that participants who viewed the modified ad understood and retained information about the drug's benefits and risks better than participants who viewed the original DTCA ad. The study suggested that risk information presented in the original DTCA ad was overwhelming for consumers.

Note: A copy of the study was provided in the board meeting materials.

Ms. Veale reported that the committee determined that while the information was useful the point of the study is beyond the committee's scope. Members also noted that pharmaceutical advertising often is used by consumers to pressure doctors to prescribe medications that may not be helpful or needed.

Mr. Schaad noted that only in the United States and New Zealand direct to consumer commercials are allowed. He also stated that in the United States the commercials have been used since 1997 and for every dollar spent on direct to consumer advertising the company makes \$4.20.

There were no comments from the public.

# Discussion and Consideration of Annual Report of the Research Advisory Panel of California

Ms. Veale explained that California Health and Safety (HSC) Code sections 11480 and 11481 require research projects using certain Schedule I and Schedule II controlled substances as their main study drugs to be reviewed and authorized by the Research Advisory Panel of California. The panel includes a member appointed by the Board of Pharmacy, Patrick R. Finley, Pharm.D.

Ms. Veale stated that the advisory panel recently submitted its annual report to the Legislature and Governor and released it online.

Note: A copy of the annual report is provided in the board meeting materials.

Ms. Veale reported that during the meeting the committee reviewed the report and took no action.

There were no comments from the board or from the public.

# k. Discussion and Consideration of Granting Continuing Education Credit for Reading The Script

Ms. Veale explained that at the November 2017 board meeting, members discussed the importance of The Script as a tool to communicate important information and training for licensees. Several members asked the committee to discuss and consider possible efforts to encourage readership, including possibly awarding CE credit for reading the newsletter.

Ms. Veale reported that at the January 31 meeting the committee agreed that Script articles provide information worthy of CE credit. It was also pointed out that the board currently awards CE to pharmacists for attending board and committee meetings.

Ms. Veale noted that the board requires two hours of CE on law and ethics. She explained that during the meeting the committee suggested that reading the newsletter could be applied to meet the requirement by awarding one CE credit for each newsletter read, up to a maximum of two hours.

Ms. Veale reported that committee members discussed how to verify reading the newsletter. Ms. Herold said pharmacists could be required to self-certify reading The Script, just as they self-certify under penalty of perjury earning CE for renewing their licenses. Another suggestion was to require pharmacists to pass a quiz included with The Script.

Ms. Veale stated that the committee directed staff to report back on the feasibility of attaching an electronic quiz to the newsletter that pharmacists would be required to complete.

Ms. Veale reported that the committee made the following motion.

**Committee recommendation:** Direct the Communication and Public Education Committee to pursue awarding CE credit for reading *The Script* that would apply to the board requirement to earn two hours of CE in law and ethics.

Mr. Schaad and Dr. Wong spoke in support of the committee's motion.

Mr. Brooks asked how the board would verify that someone has actually read The Script. Ms. Veale explained that pharmacists could be required to self-certify reading The Script, just as they self-certify under penalty of perjury earning CE for renewing their licenses. Another suggestion was to require pharmacists to pass a quiz included with The Script and keep the quiz as proof of completion.

The board discussed the possibility of having learning objectives for each issue that pharmacists must complete after reading The Script. They also asked staff to research how this can be done electronically so that the cost and staffing to implement this program would be minimal.

Board staff stated that they would work with the Department's Solid Training unit to determine if there is a way to incorporate quiz questions similarly to how they are incorporated into webinars. Staff also stated that they would research if proof of completion could be stored electronically as well as allowing pharmacists to print a certificate for their records.

President Gutierrez also recommended that the committee discuss the development of a survey so that pharmacists can provide feedback on The Script.

The board thanked Ms. Herold and Mr. Davila for their work in creating a high-quality publication for pharmacists.

**Committee Recommendation (Motion):** Direct the Communication and Public Education Committee to pursue awarding CE credit for reading *The Script* that would apply to the board requirement to earn two hours of CE in law and ethics.

Support: 9 Oppose: 0 Abstain: 0

<b>Board Member</b>	Support	Oppose	Abstain	Not Present
Brooks	х			
Butler				Х
Gutierrez	х			
Khan				х
Law	х			
Lippe	х			
Munoz	х			
Sanchez				х
Schaad	х			

Veale	х		
Weisser	х		
Wong	х		

# I. Update and Discussion of Communication and Public Education Activities by Board Staff

Ms. Veale reported that during the January 31 meeting staff updated the committee on news media and public outreach activities performed according to a communication plan for consumers and licensees.

Ms. Veale stated that a copy of the communication plan as well as a list of all the media and staff outreach activities are provided in the board meeting materials.

There were no comments from the board or the public.

#### m. Future Committee Meeting Dates

Ms. Veale provided the future committee meeting dates.

- April 25, 2018
- July 11, 2018
- October 11, 2018

#### XI. Enforcement and Compounding Committee Related Items

Chairperson Schaad provided a summary of the committee's efforts at the December 11, 2017 meeting.

## a. Discussion and Consideration of Possible Board Policy Relating to Disclosure of Enforcement Actions Involving Board Member

Chairperson Schaad explained that on the Department of Consumer Affairs' list of the "Top 10 Traits of an Effective Board Member" is "Be aware of conflicts of interest." The list clarifies that such conflicts could be real or perceived.

Chairperson Schaad stated that one area where board members should be transparent is in the area of enforcement actions (whether they are directly or indirectly involved). Board members should determine whether recusal should occur based on the real or possible appearance of self- interest. For example, an enforcement matter involving a board member could influence a member's objectivity in future decision making.

Chairperson Schaad reported that the committee determined that to ensure greater transparency, the board should provide public reporting of any enforcement action affecting a board member. Examples of items that would trigger this reporting would be disciplinary or administrative actions. Such reporting could be completed as part of the board's Organizational Development Committee's report.

Board member Lippe asked if any other boards report this information. Ms. Herold

responded that she is not aware of any board that reports the information.

Mr. Lippe asked if the reporting would only apply to situations where the board member is directly involved, not just the pharmacy they may work at. President Gutierrez explained that the intent is to report only when the board member actually is disciplined.

Ms. Freedman stated that the board could report the information in the Organizational Development report, similar to how attendance and reimbursement is currently reported.

Ms. Veale stated that she would like to see discipline for public members to be reported as well. For example, if a board member is a lawyer, any discipline on their law license should be reported.

Ms. Freedman noted that board members currently recuse themselves from disciplinary situations where the board member knows a party involved or if it involves discipline against their employer. The reporting of this information would be separate from recusal.

Ms. Veale expressed concern with how reporting the information may change the public's view of the board.

President Gutierrez clarified that only discipline that is finalized would be reported.

Mr. Brooks stated that during his time on the board he has not experienced any problems with board member discipline and he thinks that this policy may be unnecessary.

Mr. Schaad explained that many board members have received comments from licensees and the public asking the board to be more transparent and this was meant to be a step to achieve transparency.

After discussion, the board decided that the item should go back to the committee so that the committee could further discuss if the reporting of board member discipline is necessary and what should be done with the information once it is disclosed.

**Motion:** Send the item back to the Enforcement Committee for further discussion.

M/S: Brooks/Lippe

Support: 9 Oppose: 0 Abstain: 0

Ms. Freedman noted that the board had not asked for public comment before the vote. The board asked for public comment on the agenda item.

A pharmacist stated that he has to disclose any potential conflicts of interest to his employer (i.e. stocks and ownership of pharmacies). He spoke in support of board transparency. Mr. Brooks explained that board members also report annually on

financial conflicts of interest.

Due to the public comment, the board voted to reconsider the motion. There were no comments from the public or the board on the motion to reconsider.

**Motion:** Reconsider the board's previous motion of return the item back to the Enforcement Committee.

M/S: Lippe/Brooks

Support: 9 Oppose: 0 Abstain: 0

Motion: Send the item back to the Enforcement Committee for further discussion.

M/S: Brooks/Lippe

Support: 9 Oppose: 0 Abstain: 0

b. Discussion and Consideration of FDA Draft Guidance for Industry Relating to "Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier"

Chairperson Schaad reported that the Drug Supply Chain Security Act (DSCSA), signed into law in November 2013, established the federal track and trace requirements. The requirements encompass the entire drug supply chain and are phased in over a period of 10 years.

Chairperson Schaad explained that the FDA previously released a guidance document delaying some provisions of the DSCSA. Specifically, the FDA indicated that it did not intend to take action against manufacturers who do not add a product identifier to each package and homogenous case intended to be introduced into commerce before November 27, 2018. He noted that this represents a one-year delay in implementation of the track and trace requirements for manufacturers.

Chairperson Schaad reported that the committee discussed the draft guidance detailing the circumstances under which the FDA would exempt packages and homogenous cases of products to be sold that are not labeled with the required product identifier. Such products may be grandfathered if there is documentation that they were packaged by a manufacturer or repackager prior to November 27, 2018.

Chairperson Schaad stated that as part of the discussion, the committee noted that the guidance document also highlights resulting downstream changes to the remaining partners in the supply chain. Similar wholesaler requirements regarding the sale of products without the required product identifier will be delayed until November 27, 2019, and the related dispenser requirements will be delayed until November 27, 2020.

Chairperson Schaad noted that the committee was advised that information on the

delay in enforcement of these federal provisions by the FDA will be included in a future edition of *The Script*.

Note: A copy of the draft guidance was provided in the board meeting materials.

There were no comments from the board or from the public.

# c. Discussion and Consideration of "CURES 2.0 Survey of California Physicians' and Pharmacists' Experience with and Attitudes about CURES 2.0"

Chairperson Schaad stated that in September 2013, California enacted a new law to update the Controlled Substance Utilization Review and Evaluation System (CURES). This law (SB 809) provided a dedicated funding source for CURES. It also required CURES to streamline the registration process and mandated registration for dispensers and DEA-licensed prescribers.

Chairperson Schaad explained that as part of the upgrade, CURES personnel added the following new features: a streamlined electronic registration process, automatic alerts for certain high-risk prescribing practices, ability to send peer-to-peer messages within CURES, ability to flag patient-provider agreements in CURES, and ability for CURES users to identify delegates who can initiate CURES patient reports. He noted that the bundle of upgrades authorized by SB 809 is collectively referred to as "CURES 2.0."

Chairperson Schaad reported that as approved by the board at the July 2016 meeting, the board participated in assisting researchers from the University of California, Davis in surveying pharmacists. Questions were designed to learn about their use, access, likes, dislikes and concerns with CURES. Physicians also participated in a related survey at the same time. Chairperson Schaad stated that the survey also evaluated physicians' and pharmacists' attitudes about prescription drug misuse and abuse, prescribing practices, and expectations about using prescription drug monitoring programs when prescribing or dispensing controlled substances.

Chairperson Schaad reported that the committee discussed the recently published survey results as provided in the board meeting materials.

Chairperson Schaad noted that the survey results suggest that access to CURES has a major impact on pharmacists dispensing practices, and that increased professional awareness of risks and benefits plays a major role in decreased prescribing /dispensing for both physicians and pharmacists. These survey results indicate that pharmacists have near perfect compliance with mandatory CURES registration.

Mr. Weisser asked if CURES 2.0 is running smoothly. Ms. Herold responded that the system is running much better than the original CURES system and the DOJ has hired staff to provide customer service. She added that DOJ representatives will be attending the next Enforcement Committee meeting to provide a presentation on the features of the CURES 2.0 system.

There were no comments from the public.

# d. Discussion and Consideration of Noncompliant California Security Prescription Forms

Chairperson Schaad explained that the California Health and Safety Code contains specific provisions for California security forms, which are specialized prescription forms used for prescribing controlled substances in California. There are 14 security features that are required to appear on the form, and the California Department of Justice licenses the printers who are authorized to print these forms.

Chairperson Schaad reported that over the last year, the board has identified noncompliant security forms in use. When identified, the board typically cites and fines the pharmacy, and advises the prescribing board that one of its practitioners is using noncompliant forms. He explained that sometimes the board also identifies fraudulent security forms in use which are used to divert drugs or obtain them illegally. These cases are handled differently and more aggressively.

Chairperson Schaad stated that the committee was advised that in early November 2017, two pharmacy chains stopped dispensing medications when a noncompliant security form was provided. In speaking with the Department of Justice at the end of November, the board learned that in October 2017 a DOJ audit of California licensed security printers identified 12 California licensed printers that were producing security forms that were not compliant with California's Health and Safety Code.

Chairperson Schaad reported that as part of its discussion, the committee was advised that there are 33 DOJ licensed security printers and at the time of the discussion, four licensed security printers continued to print non-compliant forms. The committee discussed the two major areas of noncompliance: no checkoff box for the number of refills and absence of a watermark on the reverse of the form.

Chairperson Schaad stated that when the program was initially established, the board was responsible for approval of the security printers. However in 2006, licensure responsibility was transferred to DOJ. The committee considered if such licensure should return to the Board of Pharmacy, due to our ability to license and regulate.

Chairperson Schaad reported that the committee discussed a subscriber alert that was released by the executive officer to resolve the problem without harm to patients.

Note: A copy of the alert is included in the board meeting materials.

Ms. Herold stated that fraudulent forms pose a serious risk to public health by making it possible to divert drugs.

The board expressed its concern that pharmacists are having to act as "form police" instead of providing patient care. Ms. Herold agreed that pharmacists and doctors should be focused on patient care and stated that e-prescribing will help achieve this.

Chairperson Schaad asked if patients are being turned away if their doctor did not use

the proper form. Ms. Herold responded that unfortunately in some cases they are. She explained that the board is encouraging pharmacists to document the non-compliant form and then try to work with the prescriber to get the patient the medication. President Gutierrez added that unfortunately the patients are being caught in the middle.

A pharmacist from Ralphs stated that many of their pharmacists have seen non-compliant forms that do not have refill check boxes. Ms. Herold responded that the forms must have all of the required elements.

Ms. Veale stated that another problem she has heard about is prescriptions that are being written in a health system (for example Kaiser) but then are taken by the patient to a community pharmacy to be filled. The problem is that some of the security features are not present on the prescription because it was intended to be used within the health system.

Mark Johnson representing CVS Health stated that community pharmacists are very reluctant to fill prescriptions generated from inside a health system because they do not have all of the required security features. He asked the board to clarify the requirements for prescriptions that are generated in a health system and then are taken to a community pharmacy to be filled.

President Gutierrez asked if any discipline has been taken against a community pharmacist that fills a prescription generated from inside a health system. Mr. Johnson stated that he is not aware of any discipline.

After discussion, the board asked that the executive officer work with counsel to write an article for *The Script* on how community pharmacists should handle institutional prescriptions.

A representative from Kaiser thanked the board for providing guidance on this issue.

**Committee Recommendation (Motion):** Direct the executive officer to work with Department of Justice to ensure that prescribers are receiving compliant forms.

Support: 9 Oppose: 0 Abstain: 0

**Motion:** Direct board staff to work with legal counsel to write an article for *The Script* on institutional prescriptions forms being filled outside of the institution.

M/S: Veale/Weisser

Support: 9 Oppose: 0 Abstain: 0

e. Update on Emergency Regulations to Amend California Code of Regulations, Title 16 Section 1735.2, Related to Compounding Beyond Use Dates

Chairperson Schaad reported that during its July 2017 board meeting, the board voted to pursue an emergency regulation to amend section 1735.2 relating to

establishing beyond use dating for nonsterile drug compounded preparations.

Chairperson Schaad stated that the committee was advised that the emergency regulation took effect December 11, 2017, and will be effective for 180 days, during which time the regular rulemaking must be promulgated to make the changes permanent. Two 90-day readoptions of the emergency regulation are allowed if the board is making progress towards adopting the permanent regulations.

Chairperson Schaad explained that the permanent regulations are currently in the DCA's pre-notice review period. Board staff are monitoring progress of the pre-notice review and working with the department to address concerns as they arise.

There were no comments from the board or from the public.

Note: Ryan Brooks left the meeting at 12:20 p.m.

f. Discussion and Consideration of Draft Frequently Asked Questions Relating to Compounding Requirements, California Code of Regulations, Title 16, Sections 1735 et seq. and 1751 et seq.

Chairperson Schaad explained that as part of its ongoing evaluation of the board's compounding requirements, some requested changes were proposed and are included in the board's emergency rulemaking and/or the rulemaking to make the emergency rulemaking permanent as referenced above.

Chairperson Schaad reported that during the committee meeting members reviewed some other requested changes, and determined that a change to the regulation was not currently necessary, but additional guidance documents should be provided in the form of a FAQ. Chairperson Schaad added that the committee invited the public to submit additional topics for FAQs.

Daniel Martinez representing CPhA asked if the board's inspectors would be using the FAQs to enforce the regulations. Ms. Herold responded that the intent of the FAQs is to clarify the board's interpretation of the compounding regulations and ensure that they are being uniformly enforced. She added that if inspectors are applying the regulations differently, then this needs to be reported to her.

g. Discussion and Consideration of Requested Changes to Board Compounding Regulations, California Code of Regulations, Title 16, Sections 1735 et seq. and 1751 et seq., Including Presentation Regarding Beyond Use Date Testing

Chairperson Schaad explained that since adoption of the board's current compounding regulations, the board has received public comment regarding the impact of the regulations on patient populations, principally for oral compounded preparations, including animals.

Chairperson Schaad reported that the committee held meetings on June 2 and July 11, 2017, to consider both written and verbal comments, and requested changes offered by board staff and members of the public. As noted in prior agenda items,

the board initiated an emergency and regular rulemaking to update its regulations in response to some of the requested changes considered by the committee.

Chairperson Schaad stated that during the September 2017 committee meeting, it was requested that the committee continue its consideration of additional requested changes offered by stakeholders during previous meetings.

Chairperson Schaad reported that during its last meeting, DynaLabs provided the committee with a presentation on stability studies and potency over time. The presentation highlighted the differences between potency over time testing and stability indicating testing. The committee was advised that USP calls for stability indicating testing.

Chairperson Schaad explained that following the presentation, the committee considered possible changes to the board's current regulations.

Chairperson Schaad reviewed each section the committee discussed and any action the committee took as provided below.

#### • Proposed Change to CCR 1735(b) regarding the use of compounding kits:

The committee previously considered a change that would exempt from the definition of compounding the combining of nonhazardous ingredients from prepackaged kits supplied by an FDA-registered manufacturer for nonsterile preparations. In response to public comment, board staff was directed to contact the FDA to determine the level of regulatory oversight these kits have. Staff was subsequently advised that the FDA is not aware of any FDA approved applications for compounding kits and that the FDA has neither conducted premarket review of any instructions provided with such products nor performed any premarket review of the manufacturer's assignment of BUDs. The FDA also advised board staff that it is currently reviewing its policy in this area.

Committee Action: The committee stated the goal is to move forward with a change while making sure the kits are available and meet all standards. The committee directed staff to develop language for consideration at its next meeting.

# Proposed Change to CCR Section 1735.1(r) regarding the board's current definition of

"hazardous drug"

The committee previously considered a request to change the board's definition of "hazardous drug" to mirror the definition provided in USP <800>. In late
September 2017 USP announced the postponement of the official date of Chapter
<800> until December 1, 2019 to coincide with the anticipated update to Chapter
<797>. Consistency between the board's definition of hazardous and USP <800> would be beneficial to the board's regulated public.

Committee Action: The committee considered language that could be used to

update the board's definition of hazardous to coincide with the effective date of USP <800>:

...

(r) <u>Until December 1, 2019</u>, "Hhazardous" means all anti-neoplastic agents identified by the National Institute for Occupational Safety and Health (NIOSH) as meeting the criteria for a hazardous drug and any other drugs, compounds, or materials identified as hazardous by the pharmacist-in-charge. <u>Effective December 1, 2019</u>, "hazardous" means any drug identified by NIOSH and that exhibits at least one of

the following six criteria:

- (1) Carcinogenicity
- (2) Teratogencitiy of developmental toxicity
- (3) Reproductive toxicity in humans
- (4) Organ toxicity in low doses in human or animals
- (5) Genotoxicity
- (6) New drugs that mimic existing hazardous drugs in structure or toxicity.

...

The committee requested that board staff research USP <800> requirements and the provisions for a risk-based approach.

 Proposed Change to CCR Section 1735.2(a), regarding documentation of a prescriber's authorization to compound

During prior discussions, the committee considered if it would be appropriate to remove the requirement to document a prescriber's authorization to compound a product and requested additional research to be conducted by board staff. Without documentation neither the pharmacy nor the board will have any record that the prescriber authorized use of a compounded product. Public comment previously contemplated that such a requirement could result in a delay in therapy.

Committee Action: The committee directed staff to create language that is not burdensome or redundant to current requirements in law while focusing on consumer protection.

 Proposed Change to CCR Section 1735.2(i)(2)-(4), regarding BUDs for sterile drug products

During prior discussions, the committee considered if changes were necessary to the requirements for the establishment of a BUD for sterile products. (BUD requirements for nonsterile products are currently undergoing changes through the emergency rulemaking.) At the time of its last discussion, the committee was anticipating changes to USP <797> would be in place in 2018.

Committee Discussion: Given the delay in USP 797 changes, the committee considered changes to BUD assignments that may more closely align with current USP <797> requirements

...

- (2) For sterile compounded drug preparations, the beyond use date shall not exceed any of the following:
- (A) The shortest expiration date or beyond use date of any ingredient in the sterile compounded drug product preparation,
- (B) The chemical stability of any one ingredient in the sterile compounded drug preparation,
- (C) The chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and
- (D) The beyond use date assigned for sterility in section 1751.8., or-
- (3<u>E</u>) Extension of a beyond use date is only allowable when supported by the following: A beyond use date established by a pharmacist using his or her professional judgment after conducting research and analysis and preparing documentation. The pharmacist's documentation must demonstrate that:
- (A i) The beyond use date is supported by a USP <671> compliant Method Suitability Test,
- (Bii) The beyond use date is supported by a USP <1191> Container Closure Integrity Test, and
- (Ciii) The beyond use date is supported by Stability Studies, and
- (4<u>iv)</u> In addition to the requirements of paragraph three (3), <u>T</u>the drugs or compounded drug preparations tested and studied shall be identical in ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation.

...

Committee Action: The committee asked board staff to research the impact to patients who need more than one dose and look for alternatives.

• Proposed Change to CCR Section 1735.6(e), regarding the venting requirements for hazardous drug compounding.

The board's current regulations require hazardous compounding (among other requirements) must be completed in an externally vented, physically separated room and that each PEC in the room shall also be externally vented. [Note: This is one of two provisions where the board has established the authority for a pharmacy to secure a temporary waiver to complete construction necessary to comply.] Board staff received questions about the venting requirements and was recently advised that the board's application of the requirement (which allows a single venting system for both the PEC and the room) is consistent with OSHPD's. Specifically, OSHPD advised board staff that there is nothing in the code or USP that prevents a designer from venting the room through the hood and noted that the key is to ensure that the design would not violate the hood's listing

requirements to be able to maintain its ISO-5 environment.

Committee Discussion: The committee was advised that board staff received information that the board's requirements should be placed in the Building Standards Code.

Committee Action: Board staff will be working with legal counsel to determine if such a change is necessary and if so, the best strategy for implementation.

## Proposed Change to CCR Section 1751.4(d) regarding decontamination requirements and cleaning frequency.

In response to questions submitted previously, it was suggested that the board consider detailing contamination requirements as well as reconsider the frequency of cleaning of some surfaces and areas.

Committee Discussion: The committee considered proposed language that that could be used to update such requirements.

•••

- (d) Cleaning shall be done using a germicidal detergent and sterile water. The use of a sporicidal agent is required to be used at least monthly. When hazardous drugs are being compounded, decontamination with an inactivating agent shall take place before each cleaning. Any dilution of the germicidal detergent, sporicidal agent, or inactivating agent shall only be done with sterile water.
- (1) All ISO Class 5 surfaces, work table surfaces, carts, counters, and the cleanroom floor shall be cleaned at least every 48 hours and at minimum must be cleaned each day prior to compounding.at least daily. After each cleaning, disinfection using a suitable sterile agent shall occur on all ISO Class 5 surfaces, work table surfaces, carts, and counters.
- (2) Walls, ceilings, storage, shelving, tables, stools, and all other items in the ISO Class 7 or ISO Class 8 environment, and the segregated sterile compounding areas shall be cleaned at least monthly.
- (3) Cleaning shall also occur after any unanticipated event that could increase the risk of contamination.
- (4) All cleaning materials, such as wipers, sponges, and mops, shall be non-shedding and dedicated to use in the cleanroom, or ante-area, and segregated sterile compounding areas and shall not be removed from these areas except for disposal.

...

Committee Action: The committee directed board staff to conduct more research to present to the committee, at a future meeting.

# Proposed Change to CCR Section 1751.7(e)(1) regarding alternative testing methods and end product testing requirements

The committee has previously considered whether a rapid microbial test method may be appropriate to consider. Such testing, when used and applied appropriately can provide test results much more quickly than current testing requirements which could address some concerns raised about delays in therapy.

Committee Discussion: The committee considered language that would allow for alternative testing methods and provided below.

...(e)(1) Batch-produced sterile drug preparations compounded from one or more non-sterile ingredients, except as provided in paragraph (2), shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. Sterility testing shall be USP chapter 71 compliant <u>unless a validated rapid microbial method (RMM) test is performed</u> and pyrogens testing shall confirm acceptable levels of pyrogens per USP chapter 85 limits, before dispensing. <u>Validation studies (method suitability) for each formulation using a RMM test shall be kept in a readily retrievable form at the licensed location.</u> This requirement of end product testing confirming sterility and acceptable levels of pyrogens prior to dispensing shall apply regardless of any sterility or pyrogen testing that may have been conducted on any ingredient or combination of ingredients that were previously non-sterile. Exempt from pyrogen testing are topical ophthalmic and inhalation preparations.

•••

Also related to this section, the committee has previously considered if the board should expand its current exception for end product testing of non-sterile to sterile batch preparations. Given that pharmacies need to provide compounded preparations when a drug is in short supply, a limited exception for such instances may be appropriate. The committee considered the below language that could be used to create such an exception.

..

- (2) The following non-sterile-to-sterile batch drug preparations do not require end product testing for sterility and pyrogens:
- (A) Preparations for self-administered ophthalmic drops in a quantity sufficient for administration to a single patient for 30 days or less pursuant to a prescription.
- (B) Preparations for self-administered inhalation in a quantity sufficient for administration to a single patient for 5 days or less pursuant to a prescription.
- (C) Preparations noted as "Currently in Shortage" on the FDA website for a single patient on a one-time basis for 21 days or less pursuant to a prescription. The pharmacy shall retain a copy of the documentation of the shortage and the specific medical need as part of the pharmacy record.

Committee Action: In response to public comment regarding irrigation solutions, the committee directed board staff to research if irrigation solutions require pryrogen testing and report back to the committee its finding.

**Note:** A copy of each of the above regulation sections showing the full regulation text was provided in the board meeting materials.

President Gutierrez stated that the committee will continue to discuss these items and will make recommendations to the board. Chairperson Schaad confirmed that at

this time the Enforcement Committee does not have any recommendations for the board on these sections of the compounding regulation.

Mr. Weisser expressed his concern that the board's regulations may be preventing pharmacists from extending the BUD for simple, topical medications (i.e. diaper rash ointment). President Gutierrez stated that the pharmacist must use their professional judgement and apply findings in published studies or articles to determine if extending the BUD is appropriate.

Ms. Sodergren explained that when drafting the emergency regulations, the language regarding requirements to extend a BUD was intended to closely align with USP 797 and 797.

Mr. Weisser and Chairperson Schaad expressed concern with the practicality of the board's regulations for simple, compounded medications - including kits for medications such as magic mouthwash. Chairperson Schaad explained that pharmacists know that these compounded medications are effective, but there are often not studies available to support their use.

Dr. Wong spoke in support of the statements made by Mr. Weisser and Mr. Schaad.

The board asked that the Enforcement Committee review the requirements for extending BUDs and when a pharmacist can use his or her professional judgement. Ms. Herold asked if staff should continue to move forward with the regulation while the committee discussed the item. The board confirmed that the regulation should continue to move forward.

Daniel Martinez, representing CPhA, stated that CPhA would be bringing compounding pharmacists to the next Enforcement Committee meeting so that they can provide testimony. He added that CPhA members are concerned that the regulations are making it very difficult for community pharmacies to compound.

Mr. Martinez stated that at the July committee meeting CPhA submitted a request to exempt irrigation solutions from pyrogen testing. He asked why this has not been included in recent updates to the language. Ms. Sodergren responded that staff is currently reviewing this request and it will be brought before the committee for discussion.

President Gutierrez thanked CPhA for inviting compounding pharmacists to attend the Enforcement Committee meeting.

Ms. Herold noted that the FDA recently released a guidance document and some of the items included in the guidance document contradict the requests made by CPhA. Mr. Martinez stated that CPhA would be reviewing the FDA document to determine if CPhA needs to amend their request to the board.

A compounding pharmacist from Sutter Health stated that the board needs to amend 1735.1(r) to make the definition of hazardous drugs match the definition in USP 797 and USP 800. The board decided to discuss the definition of hazardous drugs at the

next Enforcement Committee meeting.

The compounding pharmacist explained that hospitals are spending millions of dollars to modify their compounding pharmacies to meet the board's requirements and they are having a difficult time getting answers from the board on requirements. He asked that the board add staff to answer compounding questions in a timely manner. Ms. Herold responded that many of the questions that the board receives are regarding architectural design questions, which board staff are not equipped to answer. She stated that these types of questions need to be directed to OSHPD.

President Gutierrez asked counsel to research if there is a way for the board to incorporate USP 797 into its regulations rather than creating its own language. Ms. Freedman stated that she would research the matter. Mr. Room agreed to research incorporating USP; however, he stated that he would recommend that the board draft its own regulations.

A representative from Curtis Pharma (a manufacturer of compounding kits) reported that it has secured FDA approval of one of their kits. The board asked that a representative from Curtis Pharma attend the next Enforcement Committee meeting to provide additional information.

Note: Valerie Munoz left the meeting at 1:00 p.m.

## h. Status Reports on Waivers Issued for Compounding Construction Compliance Delays Pursuant to California Code of Regulations, Title 16, Sections 1735.6 and 1751.4

Chairperson Schaad explained that title 16 of California Code of Regulations (CCR) section 1735.6 (f) states that where compliance with California's compounding regulations requires physical construction or alteration to a facility or physical environment, the board may grant a waiver for a period of time to permit the required physical changes. There is a related provision in CCR section 1751.4 which provides the same allowances for sterile compounding facilities.

Chairperson Schaad stated that an application for any waiver must be made in writing, identify the provisions requiring physical construction or alteration, and provide a timeline for any such changes. The board is able to grant the waiver for a specified period when, in its discretion, good cause is demonstrated for the waiver.

Chairperson Weisser reported that since the waiver process began, 415 waivers have been approved. Board staff continues to receive a relatively low number of new requests. He added that as implementation of the waivers transitions to a monitoring phase, board staff is now undertaking review of status reports that are documenting progress of an entity to achieving compliance.

A member of the public asked if facilities need to apply for an extension if they cannot complete construction by July 1, 2018. Ms. Herold confirmed that they would need to apply for an extension if they cannot complete construction by July 1, 2018.

#### i. Enforcement Statistics

Chairperson Schaad reported that the board received 1306 complaints and has closed 1459 investigations. The board has issued 103 Letters of Admonishment, 1,035 Citations and referred 185 cases to the Office of the Attorney General. The board has secured three interim suspension orders, been granted six penal code 23 suspensions, and issued one cease and desist. Further, the board has revoked 54 licenses, accepted the disciplinary surrender of 28 licenses, and imposed other levels of discipline against 75 licensees.

Note: The complete enforcement statistics report was provided in the board meeting materials.

There were no comments from the board or from the public.

#### j. Future Committee Meeting Dates

Chairperson Schaad provided the following future committee meeting dates.

- March 28, 2018
- June 7, 2018
- September 5, 2018
- December 13, 2018

Chairperson Schaad expressed concern that the board is becoming too focused on punishment and not on consumer protection. He asked that at the next Enforcement Committee meeting staff provide a report on the citation and fine process.

#### XII. Executive Officer's Report

#### a. Update on the Joint DEA and Board of Pharmacy Training Events

Ms. Herold reported that on January 27, the board's staff provided a Prescription Drug Abuse continuing education program at UCSF. There were 300 individuals who preregistered to attend this program, and 230 who attended. Those who attended were awarded 6 units of CE on such topics as corresponding responsibility, preventing drug losses and diversion and current drugs of abuse. Elements of DEA and board inspections are also part of the presentation. The program also included a seventh unit of CE for those who attended the naloxone training for pharmacists provided by Nathan Painter, PharmD, of UCSD.

Ms. Herold stated that this highly popular program continues to earn high evaluations from attendees for its content and speakers. She noted that through these presentations in the last year, the board has trained approximately 700 pharmacists to provide naloxone under their own authority.

There were no comments from the board of from the public.

#### b. Update on CURES

Ms. Herold reported that on February 6 she will be speaking before the Assembly Committee on Business and Professions in a hearing titled: "CURES 2.0 and Beyond: Advancing Technology to Combat the Opioid Crisis." The purpose of the hearing is to discuss how the state's upgrade to CURES is working to prevent the diversion and abuse of controlled substances, and the role licensed health care providers play in addressing the opioid epidemic. Another element is how patient privacy is maintained when accessing CURES.

Ms. Herold reviewed the statistics below on CURES usage as of December 31, 2017, there were:

- 39,878 pharmacists registered to access CURES (22.9 percent of the total of those registered to access CURES).
- 635,731 patient activity reports run by pharmacists (59.9 percent of the total PAR reports run).
- 259,937 pharmacist-initiated look ups (60.8 percent of the total number of times a health care provider accessed CURES).

There were no comments from the board or from the public.

# c. Report on the National Association of Boards of Pharmacy's (NABP) Law Enforcement and Legislation Committee Meeting

Ms. Herold stated that she was recently appointed to serve on a two-day task force with representatives from other state boards of pharmacy to refine language for NABP's model language for pharmacy practice. Amendments were made for five areas of pharmacy law that will be unveiled at the NABP May 2018 Annual Meeting.

There were no comments from the board or from the public.

#### d. Report on the Federation of Associations of Regulatory Boards Meeting

Ms. Herold reported that at the end of January, she attended the Federation of Associations of Regulatory Boards Annual Meeting in San Diego. This training session included segments on the North Carolina Dental Board Decision, the FTC's ongoing concerns with unnecessary regulation that can impede market entry and competition, economic effects of occupational licensure, and mobility and portability of practice and licensure across state lines. She noted that she was the only regulator from California present despite the location of the meeting.

There were no comments from the board of from the public.

#### e. Discussion and Consideration of Newly Released FDA Guidance Documents

Ms. Herold explained that in January 2018, the FDA released three guidance documents dealing with compounding and outsourcing regulation. A policy brief detailing plans for the FDA's future activities in these areas was also released as part

of this package. Ms. Herold stated that these items will be scheduled for detailed discussion at the next Compounding and Enforcement Committee.

There were no comments from the board or from the public.

# f. Update to the Biannual Report of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE) Examination Statistics and the North American Pharmacist Licensure Examination (NAPLEX)

Ms. Herold stated that included in the board meeting materials are performance statistics on those who took the CPJE and/or NAPLEX for California since April 2017. She explained that there was an inadvertent omission of data in the data presented to the board in November so the board is being presented with the corrected data at this meeting.

There were no comments from the board or from the public.

#### g. Settlement of People v. Target Corp., Regarding Pharmacist Consultations

Ms. Herold reported that late in 2017, the District Attorney Offices of San Diego, Riverside and Alameda Counties concluded another failure to consult undercover investigation involving pharmacies. This is the fourth such settlement pursued under the state's unfair business practices statutes. This time the settlement involves Target Corporation, going back to the time when Target operated the pharmacies in its retail stores. Target settled the case for \$41,250 to each of the three county district attorney offices, \$5,000 to the Board of Pharmacy, and \$2,500 to the Consumer Protection Prosecution Trust Fund.

Ms. Herold noted that a copy of the settlement was provided in the board meeting materials.

There were no comments from the board or from the public.

#### h. Future Sterile Compounding Training for Board Inspectors

Ms. Herold stated that the board is continuing to provide ongoing training to board inspectors on compounding. Most board inspectors have completed and passed inperson, hands-on aseptic technique training. Later this year, the board will provide all inspectors with training that will result in their becoming certified as California sterile compounding inspectors following completion of a three-day in-person training following 40 hours of web-based instruction.

There were no comments from the board or from the public.

#### i. Personnel Update

Ms. Herold briefly provided the board with a personnel update as provided below.

Recent Hires/Transfers/Promotions

- Katrina Trinchera was promoted to a SSM I over Licensing Unit B.
- Angelita Acosta was promoted to AGPA in Licensing Unit A for Sterile Compounding.
- Lupe Baltazar joined the board as an AGPA in the Enforcement Unit.
- Pamela Kemp joined the board as an AGPA in the Enforcement Unit.
- Autumn Ammann joined the board as an AGPA in the Complaint Unit
- Josh Monforte joined the board as an OT in the Enforcement Unit.

#### Departures

- Lisa Chullino, AGPA, left the board in November.
- Krystal Kimberly, OT, left the board in December.
- Adenike Adekola-Perry, Seasonal, left the board in December
- Addie Ardalan, Seasonal, left the board in January

#### Recruitments

- One AGPA for Licensing Unit A.
- One SSA for the Licensing Unit B.
- One OT for Administration Unit

#### XIII. Organizational Development Committee

### a. Budget Update/Report

President Gutierrez reported that the new fiscal year started July 1, 2017. The board's authorized expenditures for the year are \$22,317,000.

President Gutierrez stated that as discussed on the first day of the board meeting, to date the board has not been provided with budget information due to delays caused by the new Fi\$Cal accounting system.

The board asked staff to continue to work with the department on obtaining current budget information.

#### b. Board Member Reimbursement and Attendance Information

President Gutierrez stated that board member reimbursement and attendance information were provided in the board meeting materials for review by the members and the public.

There were no comments from the board or from the public.

## c. Future Board Meeting Dates

President Gutierrez reported the following board meeting dates.

- March 27, 2018 Petitioner Board Meeting
- May 2-3, 2018
- June 6, 2018 Petitioner Board Meeting

- July 24-25, 2018
- September 6, 2018 Petitioner Board Meeting
- October 23-24, 2018
- December 12, 2018 Petitioner Board Meeting

President Gutierrez adjourned the meeting at 1:45 p.m.